UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,840	09/23/2003	Paul Alfred Dickinson	CARP-0108	4976

23377 7590 10/20/2004

WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE, 46TH FLOOR
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,840	DICKINSON ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Preliminary Amendment received on September 23, 2003 and the Information Disclosure Statement of April 15, 2004 is acknowledged. Claims 1-35 stand cancelled. Claims **36-65** are pending in this application.

Claim Objections

Claims 50 and 65 respectively are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims "an amino acid, a derivative thereof", which is vague and indefinite. One of ordinary skill would not be apprised of the metes and bounds of the invention since the specification does not clearly define what the scope of "derivatives" encompass.

Claims 41 and 56 recite a method of making the aerosol formulation. The claims recite: combining (i) said medicament in an amount sufficient to provide a plurality of therapeutically effective doses; (ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and (iii) said suspension-enhancing

material in an amount effective to enhance the suspension quality of the formulation; and (b) dispersing components (i), (ii), and (iii). The intended limitation of the phrase "to provide a plurality of therapeutically effective doses" and "to propel a plurality of said therapeutically effective doses" is vague and unclear. It is unclear what "plurality" encompasses. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-65 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,725,841 to Duan et al.

Duan et al discloses an aerosol formulation containing a particulate drug, a propellant, and a dispersing aid derived from a hydroxyacid, mercapto acid, or an amino acid, wherein the formulation does not flocculate, cream, or settle quickly. See abstract and column 2, lines 6-20.

The amino acid derivative has the general formula described on column 3, lines 50-55 and column 6, lines 17-45. The most preferred amino acid residues include glycine, valine, leucine, serine, etc. . see column 6, lines 48-55. The dispersing aid is used in a concentration of 0.001 to 1 part based on 100 parts by weight of the propellant. The examples contained a concentration of 0.05% of the dispersing agent. See examples 35-38.

The propellant of choice is instant HFC-143a (1,1,1,2-tetraflurothane or HFC-227 (1,1,1,2,3,3,3-heptafluropropane). Duan et al discloses the instant drugs 38, 48, 52, and 63. see column 8, lines 22-35 and examples.

The formulations are be prepared by combining (i) the drug in an amount sufficient to provide a plurality of therapeutically effective doses; (ii) the dispersing aid; (iii) the propellant in an amount sufficient to propel a plurality of doses from an aerosol canister; and (iv) any further optional components; and dispersing the components. The components can be dispersed using a conventional mixer or homogenizer, by shaking, or by ultrasonic energy. See column 10, lines 20-35. Duan discloses metered dose valves on aerosol canisters to deliver the formulations. See column 10, lines 35-40.

Lastly, Duan discloses the formulations can be delivered to the respiratory tract and/or lung by oral inhalation in order to effect bronchodilation or in order to treat a condition susceptible of treatment by inhalation, e.g., asthma, chronic obstructive pulmonary disease. The formulations of the invention can also be delivered by nasal inhalation in order to treat, e.g., allergic rhinitis, rhinitis, or diabetes. See column 10, lines 59-65.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-37, 39-48, 50-52, 55-63, and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,655,379 to Clark et al.

Clark et al disclose an aerosolized active agent delivery, which may be formulated into a dry powder, a nebulizer, or admixed with a propellant. See abstract. The active agent may be dissolved or suspended in the propellant. Clark incorporates US patent 5,672,581 to teach the

propellant system. See column 7, lines 15-20. Clark also discloses the use of metered dose inhalers. See column 7, lines 60-67.

Instant active agents (albuterol, budesonide, flunisolide) are disclosed on column 4, lines 54-60 and example 5. Clark discloses the use of pharmaceutical carriers to improve the dispersibility of the powder within the device to provide for a more efficient and reproducible delivery of the active agent. Amino acids such as glycine, arginine, lysine, etc. and peptides such as HSA and gelatin are taught as suitable carriers with glycine and HAS (human serum albumin) are preferred. See column 6, lines 36-65.

Clark discloses combining glycine or HAS to prepare the active agent. HAS is used in an amount of 6.75% with heparin. See column 9 in its entirety. The amorphous powder is then used as a dry powder, a nebulizer, or suspended in a propellant.

Lastly, Clark et al discloses delivery of insulin to the lungs to treat diabetes. See column 2, lines 49-55.

It should be noted that HAS is a protein that inherently contains amino acids derivatives and thus reads on applicant's amino acid enhancing material.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

Gary S. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600